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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,241	07/31/2003	J. Kenneth Burkus	4002-3366/PC361.16	1607
52196	7590	12/22/2005	EXAMINER	
KRIEG DEVAULT LLP			SHAFFER, RICHARD R	
ONE INDIANA SQUARE, SUITE 2800			ART UNIT	
INDIANAPOLIS, IN 46204-2709			PAPER NUMBER	

3733

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/631,241	Applicant(s) BURKUS ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-23 and 27-41 is/are pending in the application.
- 4a) Of the above claim(s) 37-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-23 and 27-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/31/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

It is acknowledged that applicant has elected claims 16-23 and 27-36 directed to **Invention I** without traverse. Claims 37-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 30th, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-23 and 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Patent 5,797,909) in view of Kohrs, et al (US Patent 5,865,847).

Michelson discloses a method for preparing a spinal disc space for insertion of an implant to restore a desired lordotic angle comprising: inserting a guide sleeve (1310; Figures 36-41) from an anterior approach; the guide sleeve having a working channel (1352 and 1354 overlapping); distracting the disc space by inserting first and second distractors having flat sides (Column 38, Lines 7-15) or being knurled, irregularly shaped cylinders, or partial cylinders (Column 39, Lines 2-5); the partial cylinders would

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include a recess along the entire length of the body, or would a flat side in reference to material missing from a complete cylinder; preparing a first disc space through one side of the working channel (Column 38, Lines 15-21); removing the first distractor leaving a substantially cylindrical opening and then inserting an optional reamer (Column 38, Lines 27-31 and Column 16, Lines 10-16) into the first disc space through the working channel; the optional reamer is secured within the working channel by being of the size of the internal dimension of the working channel; inserting a threaded implant (Column 38, Lines 39-43) into the prepared disc space and is held in place (engaged) by the threads with the adjacent spinal end plates; repeat process for the other disc space (Column 14, Lines 60-62; Column 16, Lines 58-60; Column 38, Lines 52-65); a first embodiment (Column 37, Lines 46-52) has the guide sleeve inserted after the distractors have been inserted; an optional embodiment (Column 16, Lines 9-25), the guide sleeve and distractors can be inserted simultaneously with the use of an impaction cap.

Michelson fails to disclose an implant tapered to restore lordosis, but rather demonstrated that the distractors could be tapered to restore lordosis as well as hinting (Column 38, Lines 1-5) that other shapes are within the scope of his invention. Kohrs, et al teaches a tapered spinal implant (Figure 1) and states (Column 1, Lines 30-45) that "it is desirable to provide an implant which maintains or achieves a desired lordosis between opposing vertebrae." It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the tapered implant teaching of Kohrs, et al to further restore lordosis in the method of Michelson by not only distracting the

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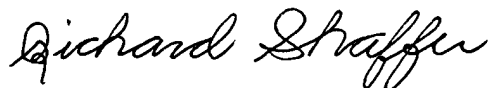
vertebral space in lordosis, but to also maintain it with an appropriately structured implant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard Shaffer
December 20th, 2005



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700